



Patent
Attorney's Docket No. 024916-011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

OCT 31 2003

In re Patent Application of)

Anthony M. JEVNIKAR et al.)

Group Art Unit: 1644

Application No.: 10/005,073)

Examiner: Gerald R. Ewoldt

TECH CENTER 1600/2900

Filed: December 7, 2001)

Confirmation No.: 8806

For: METHODS AND PRODUCTS FOR
CONTROLLING THE IMMUNE
RESPONSES IN MAMMALS)

REPLY TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS
TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a Reply to Restriction and Election of Species Requirements for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ A Terminal Disclaimer and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are _____.

☐ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$385.00 (2801) ☐ \$770.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

- ☐ Applicant(s) requests suspension of action by the Office until at least ___, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.
- ☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.
- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below:

AMENDED CLAIMS					
	NO. OF CLAIMS	HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADD'L FEE
Total Claims	50	MINUS 50 =	-0-	× \$18.00 (1202) =	-0-
Independent Claims	6	MINUS 6 =	-0-	× \$86.00 (1201) =	-0-
If Amendment adds multiple dependent claims, add \$290.00 (1203)					
Total Claim Amendment Fee					
If small entity status is claimed, subtract 50% of Total Claim Amendment Fee					
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					-0-

☐ A total fee in the amount of \$ _____ is enclosed.

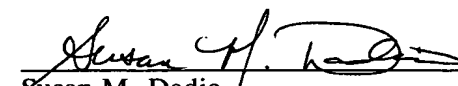
☐ Charge \$ _____ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: October 27, 2003

By: 
Susan M. Dadio
Registration No. 40,373

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For: METHODS AND PRODUCTS FOR)
CONTROLLING THE IMMUNE)
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REPLY TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In complete response to the Official Action mailed on September 26, 2003,
requiring restriction pursuant to 35 U.S.C. § 121 and election of species, Applicants offer
the following reply.

Applicants hereby elect, with traverse, to prosecute the invention of Group II,
claims 63-71, 78-83, and 95-96. The elected claims are drawn to a pharmaceutical
composition for suppressing the immune response of a mammal to an antigen, and to an
edible plant material.

As provided in section 803 of the Manual of Patent Examining Procedure
("M.P.E.P."), there are two criteria for a proper requirement for restriction: (1) the
inventions must be independent or distinct; **and** (2) there must be a serious burden on the
Examiner if restriction is required. In this case, the restriction requirement is improper

because at least the search and examination of all of the pending claims can be made without serious burden. The lack of a serious burden is particularly evident when the issued claims of the parent application are reviewed — Application Serial No. 08/617,874, now U.S. Patent No. 6,338,850. The issued claims of the parent '850 patent includes claims drawn to a method for suppressing or reducing the immune response of a mammal, a pharmaceutical composition, a transgenic plant, and an edible plant material. These are the same classes of claims which in this divisional application are being restricted into three different groups. It is unclear how now there could be a serious burden to examine all these classes of claims together in the present application when there was obviously no serious burden in the parent application. In light of the above, examination of all of the currently pending claims (Groups I, II, and III) together in the same application is respectfully requested.

At a minimum, however, the method claims of Group I should be examined with the product claims of elected Group II. As mentioned above, elected Group II includes claims drawn a pharmaceutical composition for suppressing the immune response of a mammal to an antigen. The pharmaceutical composition comprises, in oral or enteral dosage form,

an effective immunosuppressive dose of a plant tissue or partially purified plant tissue extract containing said antigen or an immunosuppressive fragment thereof and a pharmaceutically acceptable carrier, said plant tissue or partially purified plant tissue extract being obtained from a transgenic plant expressing said antigen or immunosuppressive fragment thereof.

See independent claim 63. The claims of Group I, on the other hand, are directed to a method for suppressing the immune response of a mammal to an antigen comprising:

orally or enterally administering to the mammal an effective immune suppressive dose of a plant tissue or a partially purified plant tissue extract containing said antigen or an immunosuppressive fragment thereof, said plant tissue or partially purified plant tissue extract being obtained from a transgenic plant expressing said antigen or immunosuppressive fragment thereof.

See independent claim 52. Thus, it is apparent that a search in connection with the claims of elected Group II will necessarily include a search for Group I, and *vice versa*.

Accordingly, there would be no serious burden on the Examiner to examine at least Groups I and II together in the same application.

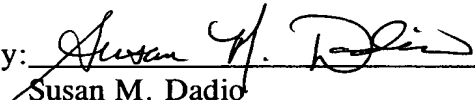
In any event, Applicants reserve the right to rejoin the claims of Group I, drawn to a method of using the elected product of Group II, at such time when the elected product claims of Group II are found allowable. See M.P.E.P. § 821.04.

With regard to the election of species requirement, Applicants hereby elect, with traverse, the transplantation antigen, in particular the Major Histocompatibility Complex (MHC) protein. In the Official action, the Examiner has indicated that applicants are required to elect "a single autoantigen or protein such as one of those listed in Claims 57 or 74[.]" See Official Action at 2 (emphasis added). Applicants have elected a single protein, *i.e.*, the MHC protein. Claim 74, however, lists various classes of the MHC protein. Applicants believe that election of the MHC protein satisfies the requirement of "a single . . . protein" and that election of a class of this protein would be unduly limiting. Nevertheless, if necessary, applicants would elect, with traverse, an MHC class II protein which would encompass the alpha and beta subunit. The claims of elected Group II which read upon the elected species include, at least, claims 63-67, 69-71, 78-83, and 95-96.

In the event that there are any questions relating to this Reply to Restriction and Election of Species Requirements or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of the application may be expedited.

Respectfully submitted,

Burns, Doane, Swecker & Mathis, L.L.P.

By: 
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Date: October 27, 2003